EXHIBIT 1

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 482, and 489

[CMS–1063–F]

RIN 0938–AM34

Medicare Program; Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals With Emergency Medical Conditions

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule clarifies policies relating to the responsibilities of Medicare-participating hospitals in treating individuals with emergency medical conditions who present to a hospital under the provisions of the Emergency Medical Treatment and Labor Act (EMTALA).

The final rule responds to public comments received on a May 9, 2002 proposed rule (67 FR 31404) that both reiterated the agency's interpretations under EMTALA and proposed clarifying changes relating to the implementation of the EMTALA provisions. These reiterations and clarifying changes related to, among other areas, seeking prior authorization from insurers for services, emergency patients presenting at off-campus outpatient clinics that do not routinely provide emergency services, the applicability of the EMTALA provisions to hospital inpatients and outpatients, the circumstances under which physicians must serve on hospital medical staff "on-call" lists, and the responsibilities of hospital-owned ambulances.

These reiterations and clarifying changes are needed to ensure uniform and consistent application of policy and to avoid any misunderstanding of EMTALA requirements by individuals, physicians, or hospital employees.

DATES: The provisions of this final rule are effective on November 10, 2003.

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I. Background

Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Social Security Act (the Act) impose specific obligations on Medicare-participating hospitals and critical access hospitals (CAHs) that offer emergency services. (Throughout this final rule, when we reference the obligation of a "hospital" under these sections of the Act and in our regulations, we mean to include CAHs as well.) These obligations concern individuals who come to a hospital emergency department and request examination or treatment for medical conditions, and apply to all of these individuals, regardless of whether or not they are beneficiaries of any program under the Act. Section 1867 of the Act sets forth requirements for medical screening examinations for medical conditions, as well as necessary stabilizing treatment or appropriate transfer. In addition, section 1867(h) of the Act specifically prohibits a delay in providing required screening or stabilization services in order to inquire about the individual's payment method or insurance status. Section 1867(d) of the Act provides for the imposition of civil monetary penalties on hospitals and physicians responsible for the following: (a) Negligently failing to appropriately screen an individual seeking medical care; (b) negligently failing to provide stabilizing treatment to an individual with an emergency medical condition; or (c) negligently transferring an individual in an inappropriate manner. (Section 1867(e)(4) of the Act defines "transfer" to include both transfers to other health care facilities and cases in which the individual is released from the care of the hospital without being moved to another health care facility.)

These provisions, taken together, are frequently referred to as the Emergency Medical Treatment and Labor Act (EMTALA), also known as the patient antidumping statute. EMTALA was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). Congress enacted these antidumping provisions in the Social Security Act because of its concern with an "increasing number of reports" that hospital emergency rooms were refusing to accept or treat individuals with emergency conditions if the individuals did not have insurance:

"* * * the Committee is most concerned that medically unstable patients are not being treated appropriately. There have been reports of situations where treatment was simply not provided. In numerous other situations, patients in an unstable condition have been transferred improperly, sometimes without the consent of the receiving hospital.

"There is some belief that this situation has worsened since the prospective payment system for hospitals became effective. The Committee wants to provide a strong assurance that pressures for greater hospital efficiency are not to be construed as license to ignore traditional community responsibilities and loosen historic standards.

"[Under the statute] [a]ll participating hospitals with emergency departments would be required to provide an appropriate medical screening examination for any individual who requests it (or has a request made on his [or her] behalf) to determine whether an emergency medical condition exists or if the patient is in active labor." (H.R. Rept. No. 99–241, Part I, 99th Cong., 1st Sess. (1985), p.27.)

In addition, section 1867(d)(2) of the Act provides for a private right of enforcement for any individual who is harmed as a "direct result" of a violation of the Act. In enacting this section of the law, Congress did not intend for the statute to be used as a Federal malpractice statute. Indeed, many courts are in agreement that EMTALA is not a Federal malpractice statute (for example, *Bryan* v. *Rectors and Visitors of University of Virginia*, 95 F.3d 349, 351 (4th Cir. 1996); *Lopez-Soto* v. *Hawayek*, 175 F.3d 170, 177 (1st Cir. 1999); and *Baker* v. *Adventist Health, Inc.*, 260 F.3d 987, 994 (3rd Cir. 2001).

The regulations implementing section 1867 of the Act are found in 42 CFR 489.24, Special responsibilities of Medicare hospitals in emergency cases. Existing § 489.24 provides for the following:

- Requires that when an individual presents to a hospital's emergency department and a request is made on the individual's behalf for examination or treatment of a medical condition, the hospital must provide for an appropriate medical screening examination to determine whether or not an emergency medical condition exists. (Paragraph (a))
- Defines certain terms, including "comes to the emergency department," "emergency medical condition," "stabilized," and "to stabilize." (Paragraph (b))
- Addresses procedures a hospital must follow when it determines, with respect to a patient, that an emergency medical condition exists. If the hospital determines that an emergency medical condition exists, the hospital must provide for further medical examination and treatment as required to stabilize the individual. If the hospital does not have the capabilities to stabilize the individual, an appropriate transfer to another facility is permitted. (Paragraph (c)) A transfer is appropriate when the medical benefits of the transfer outweigh the medical risks of the transfer and other requirements, specified in the regulations, are met. (Paragraph (d)) In addition, the hospital may transfer an unstable patient who makes an informed written request. A hospital may not delay an appropriate medical screening examination, or further examination or treatment, to inquire about the patient's payment method or insurance status. (Paragraph (c))

In addition, § 489.24 addresses: (a) Restriction of a transfer until the individual is stabilized; (b) the responsibilities of the receiving hospital; (c) termination of the provider agreement for failure to comply with EMTALA requirements; and (d) matters concerning consultation with Quality Improvement Organizations (QIOs). (Paragraphs (d) through (h), respectively)

Some EMTALA-related requirements are implemented under regulations at §§ 489.20(l), (m), (q), and (r)(1), (r)(2), and (r)(3). Those regulations deal with

a hospital's obligations to report the receipt of patients whom it has reason to believe may have been transferred inappropriately; to post signs in the emergency department describing an individual's rights to emergency treatment under section 1867 of the Act; and to maintain patient records, physician on-call lists, and emergency room logs. We are including this brief description for informational purposes but, because we are not changing the regulations in § 489.20, they will not be discussed further in this document.

In promulgating these cited regulatory sections and in enforcing the provisions of EMTALA, we are aware of the necessary balance between the hospital's and a physician's legal duty to provide examination and treatment (both under the statute and under the common law) and the practical realities of the manner in which hospitals and medical staffs are organized and operated on a day-to-day basis, as well as proper mobilization of resources within hospitals in order to comply with these legal duties. Reports of overcrowding are common in many parts of the country. Within the requirements of EMTALA, individuals should be treated at the appropriate site of care.

Hospitals and physicians have now had over 15 years of experience in organizing themselves to comply with the provisions of EMTALA. Therefore, in a proposed rule published in the **Federal Register** on May 9, 2002 as part of the annual proposed rules for the acute care hospital inpatient prospective payment system (67 FR 31469), we solicited comments from hospitals, physicians, patients, and beneficiary groups on certain proposed changes to the EMTALA policies as discussed in sections III. through XIV. of this preamble.

II. Special Advisory Bulletin on EMTALA Obligations

On November 10, 1999, CMS (then HCFA) and the Office of the Inspector General (OIG) published jointly in the **Federal Register** a Special Advisory Bulletin addressing the requirements of the EMTALA statute and the obligations of hospitals to medically screen all individuals seeking emergency services and to provide stabilizing medical treatment as necessary to all individuals, including enrollees of managed care plans, whose conditions warrant it (64 FR 61353). The Special Advisory Bulletin addressed issues of dual staffing of hospital emergency rooms by managed care and nonmanaged care physicians, prior authorization requirements of some managed care plans, use of advance beneficiary notices (ABNs) or other financial responsibility forms, handling of individuals' inquiries about financial liability for emergency services, and voluntary withdrawal of a treatment request. Although it did not amend the Code of Federal Regulations, the Special Advisory Bulletin informs individuals of HHS policy regarding application of the EMTALA statute and offers advice on the best practices to follow to avoid violation of the requirements imposed under that statute.

As discussed further in section V. of this preamble, in the May 9, 2002 proposed rule, we proposed to codify certain policies on prior authorization that are currently stated only in the Special Advisory Bulletin. We believe these changes in the regulations are needed to ensure uniform and consistent application of policy and to avoid any misunderstanding of EMTALA requirements by patients, physicians, or hospital employees.

III. Summary of the Provisions of the May 9, 2002 Proposed Rule Relating to EMTALA and Hospital Responsibility for Communication With Medicare+Choice Organizations Concerning Post-Stabilization Care Services

A. Summary of the Proposed Provisions Relating to EMTALA

Recently, a number of questions have been raised about the applicability of § 489.24 to specific situations. These questions arise in the context of managed care plans' requirements for prior authorization, case experiences involving elective procedures, and situations where individuals have been admitted as inpatients without being stabilized, or patients who had been stabilized later experience a deterioration in their medical condition. Some hospitals are uncertain about whether various conditions of participation (CoPs) found in 42 CFR part 482 apply to these situations or whether the EMTALA requirements included in the provider agreement regulations at § 489.24 apply, or both. Some representatives of the provider community have asked us to reexamine CMS policy on the applicability of EMTALA to physicians who are "on call" and to hospitals that own ambulances when those ambulances operate under communitywide emergency medical services (EMS) protocols.

To help promote consistent application of the regulations concerning the special responsibilities of Medicare-participating hospitals in emergency cases, in the May 9, 2002 proposed rule (67 FR 31469), we proposed changes to § 489.24 to clarify its application in these situations and at the same time address concerns about EMTALA raised by the Secretary's Advisory Committee on Regulatory Reform. These changes are discussed more fully below and include the following:

- We proposed to change the requirements relating to individuals who present with what may be emergency medical conditions at off-campus outpatient clinics and facilities that do not routinely provide emergency medical services. We believe these changes will enhance the quality and promptness of emergency care by permitting individuals to be referred to appropriately equipped emergency facilities close to such clinics, rather than being transported to the main campus emergency department, which may be located at a greater distance from the clinic.
- We proposed to clarify the extent to which EMTALA applies to inpatients and outpatients. We believe these clarifications will enhance understanding for hospitals as to what their obligations are under EMTALA, so that they more clearly understand to whom they are obligated under this provision of the statute, and whose care will be governed by the Medicare hospital CoPs.
- We proposed to clarify the circumstances in which physicians, particularly specialty physicians, must serve on hospital medical staff "on-call" lists. We expect these clarifications will help improve access to physician services for all hospital patients by permitting hospitals local flexibility to determine how best to maximize their available physician resources. We are currently aware of reports of physicians, particularly specialty physicians, severing their relationships with hospitals, especially when those physicians belong to more than one hospital medical staff. Physician attrition from these medical staffs could result in hospitals having no specialty physician service coverage for their patients. We proposed clarification of the on-call list requirements to permit hospitals to continue to attract physicians to serve on their medical staffs and thereby continue to provide services to emergency room patients.
- We proposed to clarify the responsibilities of hospital-owned ambulances so that these ambulances can be more fully integrated with citywide and local community EMS procedures for responding to medical emergencies and thus use these

posted or advertised name, meets the following requirements:

(a) Is a department of a hospital and is intended to routinely provide unscheduled medical services; or

(b) Meets any one of the following requirements:

(1) Is open 24 hours a day to provide unscheduled medical care, excluding, at its option, weekends or certain holidays;

(2) By its posted or advertised name, give the impression to the public that it provides medical care for urgent, immediate or emergency conditions; or

(3) Routinely provides ongoing unscheduled medical services for more than 8 consecutive hours for an individual patient.

Response: We have considered this suggested Arizona bill language defining urgent care centers for the State and believe it has merits for further revision of the CMS definition of "dedicated emergency department," with some modification.

Under subparagraph (2) of the revised definition in this final rule, we are adopting as one of three options that a "dedicated emergency department" may be any department or facility of a hospital, regardless of whether it is located on or off the main hospital campus, that is held out to the public as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment. We have not limited the definition to a hospital "department" because we do not believe it would be appropriate to exclude facilities that otherwise function as dedicated emergency departments from that definition solely because they may not fully meet the requirements for departments of providers in 42 CFR 413.65.

Second, under subparagraph (3) of the revised definition in this final rule, we are adopting the criterion that during the calendar year immediately preceding the calendar year in which a determination is being made, based on a representative sample of patient visits that occurred during that calendar year, the department or facility provided at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment. We are not using the Arizona bill 24-hour or 8-hour requirements because we believe an objective measure based on outpatient visits for the treatment of emergency medical conditions will be easier to understand and implement and better reflects the operating patterns of some emergency departments, including those at small or rural hospitals, or both, that may not offer treatment for emergency medical conditions continuously on a 24-hour, 7 days a week basis. (The hospital CoPs governing emergency services of hospitals (§ 482.55) and CAHs (§ 485.618) do not require that emergency departments be operated continuously. Under some circumstances, such as local shortages of emergency care personnel or limited demand for emergency services, hospitals and CAHs may choose to open and staff their emergency departments on less than a 24-hour, 7 days a week basis.)

8. Urgent Care Centers

Comment: Many commenters were concerned that hospital "urgent care centers" or "acute care centers" would be included, inappropriately, as "dedicated emergency departments" for purposes of EMTALA. The commenters stated that urgent care centers "are capable of responding to an urgent need, but not an emergency medical condition."

Several commenters suggested that only those urgent care centers that are functioning and holding themselves out to the public as an emergency department should be considered a dedicated emergency department for purposes of EMTALA.

Response: We believe it would be very difficult for any individual in need of emergency care to distinguish between a hospital department that provides care for an "urgent need" and one that provides care for an "emergency medical condition" need. Indeed, to CMS, both terms seem to demonstrate a similar, if not exact, functionality. Therefore, we are not adopting the commenters' suggestion to except urgent care centers from dedicated emergency department status. As we have discussed above, if the department or facility is held out to the public as a place that provides care for emergency medical conditions, it would meet the definition of dedicated emergency department. An urgent care center of this kind would fall under this criterion for dedicated emergency department status.

Although not specifically stated in a comment, an underlying issue is that urgent care centers, participating in Medicare through a hospital, and which operate as satellite facilities off the main hospital campus, would meet the current definition of a dedicated emergency department, but would generally not have the capacity on site to treat patients who had been screened and determined to have serious emergency conditions. In this situation, some might argue that it would be inappropriate for such a facility to refer a patient in an unstable condition to the main hospital campus (which could be 30 miles or more away and involve a lengthy ambulance ride) rather than to a nearby hospital that would be able to treat a patient.

Both under past and current rules, a transfer from an urgent care center to a nonaffiliated hospital is allowed under EMTALA where the facility at which the individual presented cannot stabilize the individual and the benefits of transfer exceed the risks of transfer and certain other regulatory requirements are met. Thus, our rules permit a satellite facility covered under the definition of dedicated emergency department, in this example, to screen and determine whether the case is too complex to be treated on site, that a lengthy ambulance ride to an affiliated hospital would present an unacceptable risk to the individual, and then conclude that the benefit of transfer exceeds the risk of transfer. In this case, the satellite facility could then transfer the individual to an appropriate nearby medical facility.

9. Evaluation and Treatment Issue

Comment: One commenter was concerned about the "evaluation *and* treatment" aspect of our proposed "dedicated emergency department" definition, and suggested that the reference to evaluation would make the definition overly inclusive, since an ambulatory clinic might have no patients *treated* as emergencies, but many *evaluated* (and ruled out) for emergencies. The commenter believed that part of *any* prudent ambulatory practice is to consider first the possibility of an emergency with *all* patients who are seen. The commenter suggested dropping the "evaluation and" portion of the definition to rely exclusively on an area's treatment of actual emergencies as the criterion.

Response: We agree that reference to evaluation may make the definition of "dedicated emergency department" overly inclusive, in that it would count any individuals coming to emergency rooms who are evaluated but not treated for such conditions to rule out emergency medical conditions. Therefore, we are limiting the objective criterion in the third part of the "dedicated emergency department" definition in this final rule to a department or facility that provides at least one-third of all its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

that this is the appropriate policy because existing hospital CoPs provide adequate, and in some cases, superior protection to inpatients. (*See* section XIII. of this preamble for a detailed discussion of regarding the hospital CoPs). In addition, numerous courts have held that EMTALA obligations end upon inpatient admission. At least two courts ruled on the identical issue after we published our May 9, 2002 proposed rule.

We also are adding language to adopt our established definition of "inpatient" in section 210 of the Medicare Hospital Manual (CMS Publication No. 10) who are also not subject to the EMTALA obligations. In addition, we are adopting as final the proposed § 489.24(d)(2) with modifications. We are clarifying that a hospital is required to provide care to its inpatients in accordance with the Medicare hospital CoPs.

X. Applicability of EMTALA to Provider-Based Entities (§§ 413.65(g)(1), 482.12(f), 489.24(b), and 489.24(i))

On April 7, 2000, we published a final rule specifying the criteria that must be met for a determination regarding provider-based status (65 FR 18504). The regulations in that final rule were subsequently revised to incorporate changes mandated by section 404 of Public Law 106–554 (66 FR 59856, November 30, 2001). However, those revisions did not substantively affect hospitals' EMTALA obligations with respect to off-campus departments.

A. Applicability of EMTALA to Off-Campus Hospital Departments (§§ 489.24(b) and (i) and § 413.65(g)(1))

1. Background

In the April 7, 2000 final rule (65 FR 18504), we clarified the applicability of EMTALA to hospital departments not located on the main provider campus. At that time, we revised § 489.24 to include a new paragraph (i) to specify the antidumping obligations of hospitals with respect to individuals who come to off-campus hospital departments for the examination or treatment of a potential emergency medical condition. As explained in the preamble to the April 7, 2000 final rule, we made this change because we believed it was consistent with the intent of section 1867 of the Act to protect individuals who present on hospital property (including off-campus hospital property) for emergency medical treatment. Since publication of the April 7, 2000 final rule, it has become clear that many hospitals and physicians continue to have significant concerns with our policy on the applicability of EMTALA to these off-campus locations.

2. Provisions of the Proposed Rule

After further consideration, in the May 9, 2002 proposed rule (67 FR 31476), we proposed to clarify the scope of EMTALA's applicability in this scenario to those off-campus departments that are treated by Medicare under § 413.65(b) to be departments of the hospital, and that are equipped and staffed areas that are used a significant portion of the time for the initial evaluation and treatment of outpatients for emergency medical conditions. That is, we proposed to narrow the applicability of EMTALA to only those off-campus departments that are "dedicated emergency departments" as defined in proposed revised § 489.24(b).

As proposed, this definition would include such departments, whether or not the words "emergency room" or "emergency department" were used by the hospital to identify the departments. The definition would also be interpreted to encompass those off-campus hospital departments that would be perceived by an individual as appropriate places to go for emergency care. Therefore, we proposed to revise the definition of "Hospital with an emergency department" at § 489.24(b) to account for these off-campus dedicated emergency departments and also to amend the definition of "Comes to the emergency department" at § 489.24(b) to include this same language. We believe these proposed changes would enhance the quality of emergency care by facilitating the prompt delivery of emergency care in those cases, thus permitting individuals to be referred to nearby facilities with the capacity to offer appropriate emergency care.

In general, we expect that off-campus departments that meet the proposed definitions stated above would in practice be functioning as "off-campus emergency departments." Therefore, we believe it is reasonable to expect the hospital to assume, with respect to these off-campus departments, all EMTALA obligations that the hospital must assume with respect to the main hospital campus emergency department. For instance, the screening and stabilization or transfer requirements described in section V.K.1. of the preamble of the May 9, 2002 proposed rule ("Background") would extend to the off-campus emergency departments, as well as to any such departments on the main hospital campus.

In conjunction with this proposed change in the extent of EMTALA applicability with respect to off-campus facilities, we also proposed to delete all of existing § 489.24(i), which, as noted above, was established in the April 7, 2000 final rule. We proposed to delete this paragraph in its entirety because its primary purpose is to describe a hospital's EMTALA obligations with respect to patients presenting to off-campus departments that do not routinely provide emergency care. Under the proposals outlined above, however, a hospital would have no EMTALA obligation with respect to individuals presenting to such departments. Therefore, it would no longer be necessary to impose the requirements in existing § 489.24(i). Even though off-campus provider-based departments that do not routinely offer services for emergency medical conditions would not be subject to EMTALA, some individuals may occasionally come to them to seek emergency care. Under such circumstances, we believe it would be appropriate for the department to call an emergency medical service (EMS) if it is incapable of treating the patient, and to furnish whatever assistance it can to the individual while awaiting the arrival of EMS personnel. Consistent with the hospital's obligation to the community and similar to the Medicare hospital CoP under § 482.12(f)(2) that apply to hospitals that do not provide emergency services, we would expect the hospital to have appropriate protocols in place for dealing with individuals who come to off-campus nonemergency facilities to seek emergency care.

To clarify a hospital's responsibility in this regard, in the May 9, 2002 proposed rule, we proposed to revise § 482.12(f) by adding a new paragraph (3) to state that if emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff of the hospital has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate. (We note that, in a separate document (62 FR 66758, December 16, 1997), we proposed to relocate the existing § 482.12(f) requirement to a new section of Part 482. The change to § 482.12(f) in this final rule will be taken into account in finalizing the December 16, 1997 proposal.) However, the hospital would not incur an EMTALA obligation with respect to the individual.

In summary, we proposed in existing § 489.24(b) to revise the definitions of "comes to the emergency department" and "hospital with an emergency

department", and to include these off-campus departments in our new definition of "dedicated emergency department." We solicited comments on whether this new term is needed or if the term "emergency department" could be defined more broadly to encompass other departments that provide urgent or emergent care services. We proposed to delete all of existing § 489.24(i) and to make conforming revisions to § 413.65(g)(1).

3. Summary of Public Comments and Departmental Responses

Comment: Numerous commenters expressed strong support for the proposal to limit the applicability of EMTALA, in cases of off-campus departments, to only those departments that qualify as dedicated emergency departments. Some commenters stated that EMTALA should not apply to an off-campus department that does not hold itself out as an emergency department. Other commenters believed this would be appropriate because a prudent layperson would not regard the department as an appropriate place at which to seek emergency care. These commenters stated that an individual with a broken arm might regard the hospital's orthopedic department as an appropriate source of care, but that this should not mean that the orthopedic department should be treated as a dedicated emergency department.

Other commenters stated that EMTALA should not apply to any off-campus department unless CMS provides a narrower definition of "dedicated emergency department" and clarifies whether or under what circumstances EMTALA will apply to urgent care facilities. However, the commenters did not provide any indication of why the definition is believed to be too broad or how they would recommend changing it.

Several commenters stated that EMTALA should not apply to an off-campus urgent care center unless the center is functioning and holding itself out to the public as an emergency department.

Response: We agree that EMTALA should apply to off-campus departments only if they qualify as dedicated emergency departments, and have addressed the commenters' suggestion as part of the revision of the definition of a dedicated emergency department. In addition, we are adopting in this final rule the proposed standard under § 482.12(f)(3) that hospitals have appropriate protocols in place for dealing with individuals who come to off-campus nonemergency facilities to seek emergency care.

Regarding the suggestion that a hospital's orthopedic department might be determined to be a dedicated emergency department because an individual person would look to it for emergency orthopedic care, as we have noted above, the definition of "dedicated emergency department" in section VIII. of this preamble does not include "prudent layperson" standard. Rather, with this final rule, "dedicated emergency department" means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that (1) is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; (2) is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or (3) during the calendar year immediately preceding the calendar year in which a determination under § 489.24 is being made, based on a representative sample of patient visits that occurred during that calendar year, provides at least one-third of all of its outpatient visits for the examination or treatment of emergency medical conditions. If the orthopedic department does not meet any of these three criteria for dedicated emergency department status, it is not a dedicated emergency department for EMTALA purposes, regardless of what the individual may believe as to the status of the department.

4. Provisions of the Final Rule

We are adopting, as final with modifications as discussed in earlier sections of this preamble, the proposed revisions of the definition of "come to the emergency department," "hospital with an emergency department," and "dedicated emergency department" at § 489.24(b), which encompass off-campus hospital departments that would be perceived by individuals as appropriate places to go for emergency care. We also are adopting as final the related proposed deletion of the provisions under § 489.24(i) and the conforming change to § 413.65(g)(1). In addition, we are adopting, as final, the proposed new § 482.12(f)(3) which provides that the governing body of a hospital must assure that the medical staff has written policies and procedures in effect with respect to off-campus departments for appraisal of emergencies and referrals, when appropriate.

B. On-Campus Provider-Based Applicability

1. Background

At existing § 413.65(g)(1), we state, in part, that if any individual comes to any hospital-based entity (including an RHC) located on the main hospital campus, and a request is made on the individual's behalf for examination or treatment of a medical condition, the entity must comply with the antidumping rules at § 489.24. Since provider-based entities, as defined in § 413.65(b), are not under the certification and provider number of the main provider hospital, this language, read literally, would appear to impose EMTALA obligations on providers other than hospitals, a result that would not be consistent with section 1867, which restricts EMTALA applicability to hospitals.

2. Provisions of the Proposed Rule

To avoid confusion on this point and to prevent any inadvertent extension of EMTALA requirements outside the hospital setting, in the May 9, 2002 proposed rule (67 FR 31477), we proposed to clarify that EMTALA applies in this scenario to only those *departments* on the hospital's main campus that are provider-based; EMTALA would not apply to provider-based *entities* (such as RHCs) that are on the hospital campus.

In addition, we proposed in § 489.24(b) to revise the definition of "Comes to the emergency department" to include an individual who presents on hospital property, in which "hospital property" is, in part, defined as "the entire main hospital campus as defined at § 413.65(b) of this chapter, including the parking lot, sidewalk, and driveway, but excluding other areas or structures that may be located within 250 yards of the hospital's main building but are not part of the hospital, such as physician offices, RHCs, SNFs, or other entities that participate separately in Medicare, or restaurants, shops, or other nonmedical facilities." We specifically sought comments on this proposed revised definition. Generally, the proposed language would clarify that EMTALA does not apply to provider-based entities, whether or not they are located on a hospital campus. This language is also consistent with our policy as stated in questions and answers published on the CMS Web site: *http://www.cms.gov* (CMS EMTALA guidance, 7/20/01, Q/A #1) that clarifies that EMTALA does not apply to other areas or structures located on the hospital campus that are not part of the hospital, such as fast food

restaurants or independent medical practices.

We stated that if this proposed change limiting EMTALA applicability to only those on-campus departments of the hospital became final, we believe that if an individual comes to an on-campus provider-based entity or other area or structure on the campus not applicable under the new policy and presents for emergency care, it would be appropriate for the entity to call the emergency medical service if it is incapable of treating the patient, and to furnish whatever assistance it can to the individual while awaiting the arrival of emergency medical service personnel. However, the hospital on whose campus the entity is located would not incur an EMTALA obligation with respect to the individual.

In the May 9, 2002 proposed rule, we solicited comments from providers and other interested parties on the proper or best way to organize hospital resources to react to situations on campus where an individual requires immediate medical attention.

We proposed in § 489.24(b) to revise the definition of "Comes to emergency department" (specifically, under proposed new paragraph (1)) and make conforming changes at § 413.65(g)(1).

In the August 1, 2002 final rule issued following the May 9, 2002 proposed rule (67 FR 50090), we only adopted as final the deletion of the second sentence of the existing § 413.65(g)(1) that address the nonapplicability of EMTALA to provider-based entities. We did not adopt other proposed clarifications concerning application of EMTALA to provider-based departments, on or off the campus, or any other proposals concerning EMTALA.

3. Summary of Public Comments and Departmental Responses

Comment: Several commenters expressed general approval of the proposed clarifications of the definition of "hospital property" for purposes of the EMTALA regulations and stated that the proposals will lead to more precise interpretation of the regulations.

Response: We agree, and are adopting the proposed clarifications as part of this final rule.

Comment: One commenter expressed strong opposition to the proposed clarification under which on-campus provider-based entities would not be subject to EMTALA. The commenter noted that individuals seeking emergency treatment may be severely confused or agitated, so that they would be unable to determine whether a particular area or facility is a dedicated emergency department, and that in some cases such individuals may also be physically unable to proceed to the dedicated emergency department. The commenter also stated that provider-based departments frequently are located close to the main hospital campus, typically receive higher reimbursement from Medicare by virtue of their provider-based status, and may be indistinguishable, especially to an individual in a crisis situation, from areas at which emergency care is provided. The commenter suggested that, in view of this, it is not unreasonable to expect the provider-based entity to assume responsibility for ensuring that individuals who present with emergency care needs receive screening and stabilization. Therefore, the commenter recommended that we require that provider-based entities either ensure that transfer to a dedicated emergency department occurs safely, or provide screening and stabilization at the entity if it is able safely to do so.

Response: We understand and share the commenter's concern for individuals seeking emergency services who come to provider-based entities for assistance, but note that the legislative provision under which EMTALA responsibilities apply (section 1867 of the Act) is specific to hospitals, and does not extend to nonhospital entities (such as rural health clinics or physician offices), even where those entities may be located adjacent to hospital facilities and owned or operated by hospitals, or both. Therefore, we are not making a revision in this final rule based on this comment.

4. Provisions of the Final Rule

We are adopting, as final with minor editorial changes as explained earlier in this preamble, the proposed revision of "come to the emergency department" and "hospital property" in which hospital property is, in part, defined as "the entire main hospital campus as defined at § 413.65(b) of this chapter, including the parking lot, sidewalk, and driveway, but excluding other areas or structures of the hospital's main building that are not part of the hospital, such as physician offices, RHCs, SNFs, or other entities that participate separately in Medicare, or restaurants, shops, or other nonmedical facilities." This will clarify that on-campus provider-based entities would not be subject to EMTALA.

We are also adopting as final without modification the proposed clarifying change to § 413.65(g)(1).

XI. EMTALA and On-Call Requirements (§ 489.24(j))

A. Background

We have frequently received inquiries concerning the statutory requirement that hospitals maintain an "on-call" list of physicians to provide services to patients who seek care in hospital emergency departments. We believe there are a number of misconceptions in the provider industry concerning these on-call requirements. Therefore, as in the May 9, 2002 proposed rule (67 FR 31478), we are including a section that clarifies what kinds of obligations physicians and hospitals have to provide on-call coverage under EMTALA.

Section 1866(a)(1)(I)(iii) of the Act states, as a requirement for participation in the Medicare program, that hospitals must maintain a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition. If a physician on the list is called by a hospital to provide emergency screening or treatment and either fails or refuses to appear within a reasonable period of time, the hospital and that physician may be in violation of EMTALA as provided for under section 1867(d)(1)(C) of the Act.

The CMS State Operations Manual (SOM) further clarifies a hospital's responsibility for the on-call physician. The SOM (Appendix V, page V–15, Tag A404) states:

- Each hospital has the discretion to maintain the on-call list in a manner to best meet the needs of its patients.
- Physicians, including specialists and subspecialists (for example, neurologists), are not required to be on call at all times. The hospital must have policies and procedures to be followed when a particular specialty is not available or the on-call physician cannot respond because of situations beyond his or her control.

Thus, hospitals are required to maintain a list of physicians on call at any one time, and physicians or hospitals, or both, may be responsible under the EMTALA statute to provide emergency care if a physician who is on the on-call list fails to or refuses to appear within a reasonable period of time. However, Medicare does not set requirements on how frequently a hospital's staff of on-call physicians are expected to be available to provide on-call coverage; that is a determination to be made between the hospital and the physicians on its on-call roster. We are aware that practice demands in treating other patients, conferences, vacations,